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IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF THE ADMINISTRATIVE LAW JUDGES

In the Matter of **DANIEL CHAPTER ONE,** **a corporation, and**	)	**DOCKET NO. 9329**
JAMES FEIJO, **individually, and as an officer of** **Daniel Chapter One.**	)	**PUBLIC DOCUMENT**

RESPONDENTS' PROPOSED FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER, AND BRIEF IN SUPPORT THEREOF

Attorneys for Respondents:

Michael McCormack
26828 Maple Valley Hwy, Suite 242
Maple Valley, WA 98038
Phone: 425-785-9446

James S. Turner
Betsy E. Lehrfeld
Christopher B. Turner
Swankin & Turner
1400 16th Street, NW, Suite 101
Washington, DC 20036
Phone: 202-462-8800
Fax: 202-26506564

Of Counsel:

Herbert W. Titus
William J. Olson
John S. Miles
Jeremiah L. Morgan
William J. Olson, P.C.
8180 Greensboro Drive, Suite 1070
McLean, VA 22102-3860
Phone: 703-356-5070
Fax: 703-356-5085

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RESPONDENTS' POST-HEARING BRIEF

As directed by this Court's Order on Post-hearing Briefs, Respondents supply the attached Findings of Fact and Conclusions of Law, which are supported by the legal analysis that appears below. Further, as directed by the Court's Order, only Findings of Fact are provided on the issue of the Commission's jurisdiction over Respondents' religious ministry. The jurisdiction issue is not addressed below or in Respondents' proposed Conclusions of Law.

For the reasons set forth below, Respondents contend that Complaint Counsel has not proven that Respondents violated 15 U.S.C. §§45 and 52 and has not established a constitutionally-valid predicate for action against Respondents. Therefore, Complaint should be dismissed with prejudice, and Complaint Counsel's proposed Order should be rejected in its entirety.

I. Complaint Counsel Has Not Shown That Respondents Violated 15 U.S.C. §§45 and 52.

This case can be summarized as follows: Complaint Counsel has presumed much and proven little of what is required of the Commission.

A. Complaint Counsel's focus on double-blind, placebo-based studies as the only basis for substantiation of dietary supplements is incorrect.

Dr. Denis Miller MD, a well known cancer research administrator, was the only substantive witness offered by Complaint Counsel. The scope of his testimony was narrow and specific. Cancer drugs, he testified, must be tested by double-blind, placebo-based clinical trials to receive approval by the US Food and Drug Administration. Complaint Counsel rests its case on the presumption that only substantiation by double-blind, placebo-controlled clinical trials, as required by the US Food Drug and Cosmetic Act for approval of drugs, qualifies as reasonable substantiation for claims made by Respondents.. Essentially, Complaint Counsel places all its eggs in this double-blind basket. It chose, contrary to law, to meet all the other required elements of proof based on presumptions. Presumptions, as set out below, fail to make the FTC case.

Even the double-blind element of proof about the purported requirement of placebo controlled, clinical studies misses the mark. The FTC Act does not require double blind, placebo-controlled studies as the basis for reasonable substantiation. In fact the Food Drug and Cosmetic Act (FDCA) itself does not require such studies for structure or function claims for dietary supplements which are allowed by the Dietary Supplement Health and Education Act (DSHEA), a 1994 amendment to the FDCA.[1]

[1] The Dietary Supplement Health and Education Act of 1994 (DSHEA) added section 403(r)(6) to the Federal Food, Drug, and Cosmetic Act.

"*Placebo-controlled, double-blind testing is not a legal requirement for consumer products.*" *FTC v. QT*, 512 F. 3d 858, 861 (7th Cir. 2008). In the *FTC v. QT* case, the U. S. Court of Appeals for the Seventh Circuit spelled out the argument graphically, saying:

> Defendants maintain that the magistrate judge subjected their statements to an excessively rigorous standard of proof. Some passages in the opinion could be read to imply that any statement about a product's therapeutic effects must be deemed false unless the claim has been verified in a placebo-controlled, double-blind study: that is, a study in which some persons are given the product whose effects are being investigated while others are given a placebo (with the allocation made at random), and neither the person who distributes the product nor the person who measures the effects knows which received the real product. Such studies are expensive, not only because of the need for placebos and keeping the experimenters in the dark, but also because they require large numbers of participants to achieve statistically significant results. Defendants observe that requiring vendors to bear such heavy costs may keep useful products off the market (this has been a problem for drugs that are subject to the FDA's testing protocols) and prevent vendors from making truthful statements that will help consumers locate products that will do them good.
>
> Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand. The burden is on the Commission to prove that the statements are false. (This is one way in which the Federal Trade Commission Act differs from the Food and Drug Act.) Think about the seller of an adhesive bandage treated with a disinfectant such as iodine. The seller does not need to conduct tests before asserting that this product reduces the risk of infection from cuts. The bandage keeps foreign materials out of the cuts and kills some bacteria. It may be debatable how much the risk of infection falls, but the direction of the effect would be known, and the claim could not be condemned as false. Placebo-controlled, double-blind testing is not a legal requirement for consumer products.

Furthermore, notwithstanding impressive credentials, Dr. Miller could not testify about the meaning of a "structure or function" claim, the distinction between health claims and structure or function claims, or any other aspects of DSHEA. The phrase "structure or function" in the context of dietary supplement claims refers to

representations about a dietary supplement's effect on the structure or function of the body for maintenance of good health and nutrition. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 26, fn. 2. The permission granted by DSHEA for Dietary Supplement Structure or Function claims is consistent with FTC standards. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 10 and fn. 3.

As described more fully below, the single-minded prosecution that Complaint Counsel has undertaken here ignores the following express FTC policies and Guidelines for dietary supplements:

- "The FTC's standard for evaluating substantiation [for dietary supplement claims] must be sufficiently flexible to ensure that consumers have access to information about emerging areas of science." *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 8.
- There is no requirement that a dietary supplement claim be supported by a specific number of studies. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 10.
- Research concerning the biological mechanism underlying the claimed action is acceptable as reasonable substantiation for claims about dietary supplements. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 10.

B. Complaint Counsel Failed to Meet Other Necessary Elements of Proof Altogether.

The shortcomings in Complaint Counsel's case extend to other elements of required proof, for Complaint Counsel has ignored its burden on several key elements, which it must prove with clear, cogent and convincing evidence.[2]

1. General Elements of Proof.

   a. The Elements of Proof under 15 USC § 45(n).

[2] The standard of proof required of the FTC in this case is *clear, cogent and convincing* evidence in light of the Constitutional liberty and property interests involved in this case. *Addington v. Texas*, 441 U.S. 418 (1970).

To prove unfairness, Complaint Counsel must prove that:

> the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence. Such public policy considerations may not serve as a primary basis for such determination.

Complaint Counsel offered not a shred of evidence to meet the requirements of 15 USC §45(n). As the relevant case law and FTC policy show, these same standards apply also to false, deceptive and misleading charges under 15 U.S.C. §45(a) and 52.

2. The Elements of Proof under the Reasonable Basis Test.

The FTC employs a reasonable basis test for determining whether an alleged advertisement is deceptive. *Pfizer, Inc.* 81 FTC 23, 62 (1972); *FTC v. Pharmatec*, 576 F. Supp. 294, 302 (DDC, 1983). The reasonable basis for a product claim differs with the particular product at issue, and depends on factors that include the degree to which consumers will rely on the claim (i.e., whether alleged harm is reasonably avoidable by consumers). *Pfizer*, at 64 and *Pharmatec*, at 302.

As a general rule, extrinsic evidence is required to prove the inference of deceptive advertising. *FTC Policy Statement on Deception*, appended *to Cliffdale Associates*, 103 FC 110, 174 (1984), hereinafter "*Cliffdale* Statement. This is particularly true on the issue of consumer perceptions or expectations, where extrinsic evidence or expert testimony is necessary to prove consumer perceptions of an advertising message. *Thompson Medical v. FTC*, 791 F.2d 189, 197 (D.C.Cir. 1986), and *FTC Policy Statement Regarding Advertising Substantiation*, appended *to Thompson Medical v. FTC*, 104 FTC 648, 839, aff'd 791 F.2d 189 (D.C.Cir. 1986), hereinafter "*Thompson* Policy Statement." The reasonableness of a representation or practice that affects or is directed

primarily to a particular group is evaluated from the perspective of a member of that group. *Cliffdale* Statement.

As with the standards required by 15 USC §45(n), Complaint Counsel produced no evidence at the hearing to meet its requirements under the "reasonable basis" test.

3. The Elements of Proof for an Overall Net Impression Case.

When the charges against a respondent are based on the "overall net impression" rather than on express claims, as is the case here, those charges must be proved by substantial evidence of consumer expectations in order for Complaint Counsel to prevail. *Thompson*[3], 791 F. 2d at 197. Accord, *Thompson* Policy Statement at p. 2.

Absent actual evidence of consumer expectations, according to the *Thompson* Policy Statement, the FTC's substantial evidence must address the following 6 factors:

- The type of claim;
- The Products;
- The consequences of a false claim;
- The benefits of a truthful claim;
- The cost of developing substantiation for the claim; and
- The amount of substantiation experts in the field believe is reasonable.

See *Thompson* Policy Statement at p. 2.

The *Thompson* Policy Statement states clearly that these factors apply to charges of false/misleading advertising, deception and unfairness. "The Commission's determination of what constitutes a reasonable basis depends, as it does in an unfairness analysis, on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include [the 6-point list described above.]"

These factors are identical to the statutory requirements of 15 USC 6§45(n) applicable to claims of unfairness. In other words, Complaint Counsel must effectively

[3] *Thompson Medical*, 104 FTC 648 (1984), aff'd 791 F. 2d 189 (D.C Cir 1986).

meet the same standards of proof for false advertising and deception, as §45(n) requires for unfairness. Agency presumptions and policy guidance alone will not suffice.

The Commission must also examine the allegedly deceptive practice from the perspective of a reasonable consumer. If the representation is directed *primarily* to a particular group, the FTC is required to examine reasonableness from the perspective of that group.[4] *Cliffdale* Statement. That is, the FTC must determine the effect of the challenged claims on a reasonable member of the target group. In this case, that group consists of individuals devoted to natural health in general and the constituents of Respondents' religious ministry in particular.[6]

When such a specific group of recipients is involved, extrinsic evidence about that group's reasonable perceptions is necessary. *Cliffdale* Statement. In *Thompson*, 791 F. 2d at 197, the Circuit Court made special note that "The issue of [consumer perception of the claims] was extensively addressed by expert testimony."

4. Specific Elements of Proof for Dietary Supplement Claims.

The Dietary Supplement Health and Education Act (DSHEA) allows dietary supplement manufacturers to make "structure or function" claims about their products:

[A] statement for a dietary supplement may be made if:

> (A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, **describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans**, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,

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[4] Note that the representation need not be directed *exclusively* to a particular group.
[6] *Cliffdale* Statement at footnotes 13 and 29.

(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

(C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.

21 USC §343(r)(6). [Bold emphasis added.]

The meaning of this statute is well settled: a natural supplement provider is lawfully allowed to make structure or function claims describing how a particular nutrient or dietary supplement may affect a structure or function of the human body. *Pearson v. Shalala*, 164 F. 3d 650 (1999); and *U.S. v. Lane Labs*, 324 F. Supp. 2d 547, 565 (D.N.J., 2004).

Furthermore, as previously stated, the FTC's position with regard to dietary supplement claims is clear:

- "The FTC's standard for evaluating substantiation [for dietary supplement claims] must be sufficiently flexible to ensure that consumers have access to information about emerging areas of science." *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 8.
- There is no requirement that a dietary supplement claim be supported by a specific number of studies. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 10.
- Research concerning the biological mechanism underlying the claimed action is acceptable as reasonable substantiation for claims about dietary supplements. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 10.

Here, Complaint Counsel has tried to ignore DSHEA and the FTC's own guidelines for dietary supplement claims. Dr. Miller's testimony related to the approval by the FDA of chemotherapeutic agents and made no reference to or claimed any

relevance to the standards that govern claims made for dietary supplements. Dr. Miller's testimony was not relevant under, and did not take into consideration, either DSHEA or the FTC's Official Guidance to the Dietary Supplement Industry, which says that the amount and type of substantiation required for dietary supplements is determined by what experts *in the relevant field* would consider to be adequate. [7] This is consistent with the qualifications required of an expert under the relevancy prong of the *Daubert* standard.[8] Dr. Miller did not even know what a structure or function claim is! (Miller, Tr. 173-174.)

In contrast, Respondents' experts Dr. Duke and Dr. LaMont are specifically qualified to testify about dietary supplements. The FTC's need for qualified expert testimony from the field of dietary supplements is drawn from the sharp distinction expressed by Congress between the regulation of dietary supplement claims on the one hand, and the regulation of drugs on the other hand. Dr. LaMont's testimony in particular demonstrated that Respondents' claims are proper structure or function claims. Nowhere on the face of the actual statements by Respondents do Respondents state that their products "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases," which are the claims prohibited by DSHEA. Each of the Respondents' statements on their face describe how the products and/or their constituent ingredients support the structure or function of the human body, e.g., as "adjuncts" to – not in lieu of - cancer or other health treatment.

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[7] *Dietary Supplements: An Advertising Guide for the Industry*, produced by Complaint Counsel as evidence of policy in this case. A copy is provided at Appendix 2, Bates no. FTC-Respondents 1041 to 1070, p. 1052, specifically.

[8] *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

C. Respondents' Substantiation Is More Than Adequate To Meet The Required Legal Standards.

Respondents substantiated their structure or function claims. As Dr. LaMont testified, the substantiation that Respondents used is supported by considerable literature in the field that constitutes adequate and reasonable corroboration for the claimed "biological mechanism underlying the claimed action." (LaMont, Tr. 587, 599.)

D. In The Absence Of Actual Harm, The FTC Must Prove Its Case With Actual Evidence Or Otherwise Violate Due Process.

There is a final point to be made about Complaint Counsel's flawed reliance on presumptions in a case involving dietary supplement structure or function claims. The principle of DSHEA is that dietary supplements are presumed safe unless and until they are proved harmful. The burden to prove harm is on the government. Complaint Counsel's approach in this case turns Congressional promulgation of DSHEA on its head by emasculating the dietary supplement providers' rights, and by ignoring the government's burden to prove harm.

Even without DSHEA, Complaint Counsel's near-exclusive reliance on presumptions in a case like this violates due process. It bears repeating: there are many factors that the FTC must consider in order to maintain charges of unfair, deceptive and misleading advertising. In circumstances like those presented here, those factors must be addressed with extrinsic evidence, including but not limited to consumer surveys, expert testimony about consumer perceptions and expert testimony qualified in the specific field of dietary supplements.

Without such extrinsic evidence, in the absence of actual harm and in the context of an "overall net impression" case, Complaint Counsel's attempt to meet nearly every element of proof by means of presumption effectively shifts the burden of proof to the Respondents. This type of procedural approach absolves the government of the most basic obligation to put on a prima facie case with competent evidence. This is unconstitutional, as it violates due process in the most fundamental of ways.

In *Mathews v. Eldridge*[9], the U.S. Supreme Court developed a three-part test to evaluate the minimum constitutional process due in a variety of procedural situations. In *Mathews* at p. 335, the Court considered whether a hearing prior to administrative termination of social security benefits was constitutionally required. The Court structured its consideration of procedural due process on three relevant factors: (1) the private interest that will be affected by the official action; (2) the risk of erroneous deprivation of such interest through the procedures used; and (3) the governmental interest in the added fiscal and administrative burden that additional process would entail.

The third of the *Mathews* factors deserves an especially close look, i.e., the added fiscal and administrative burden that additional due process procedures would entail, i.e., the requirement to produce extrinsic evidence instead of presumptions. Trial by presumption has been explicitly considered and explicitly rejected by the U.S. Supreme Court. Indeed, almost in anticipation of this 3rd element of the *Mathews* test, the U.S. Supreme Court decided *Stanley v. Illinois*[10] just a few years earlier than *Mathews*. The *Stanley* case concerned the due process requirements involved in parentage cases. The Court there addressed the specific question of whether the State could forego due process

[9] 424 U.S. 319, 332 (1976)
[10] 405 U.S. 645, 656-657 (1972).

requirements in the interest of efficiency by adopting a presumption in lieu of meeting a burden of proof. Here, in a quote that seems to have anticipated not only *Mathews* but this case also, the *Stanley* Court said:

> The establishment of prompt efficacious procedures to achieve legitimate state ends is a proper state interest worthy of cognizance in constitutional adjudication. But the Constitution recognizes higher values than speed and efficiency. Indeed, one might fairly say of the Bill of Rights in general, and the Due Process Clause in particular, that they were designed to protect the fragile values of a vulnerable citizenry from the overbearing concern for efficiency and efficacy that may characterize praiseworthy government officials no less, and perhaps more, than mediocre ones.
>
> Procedure by presumption is always cheaper and easier than individualized determination. But when, as here, the procedure forecloses the determinative issues . . . when it explicitly disdains present realities in deference to past formalities, it needlessly risks running roughshod over the important interests . . . [Such a procedure] therefore cannot stand.

Allowing Complaint Counsel to try this case by presumption in the absence of actual harm, wherein the standard is a subjective "overall net impression," improperly shifts the primary burden of proof to Respondents in violation of DSHEA, *Matthews,* and *Stanley*.

II. The First Amendment Protects the Statements Made By Respondents

Complaint Counsel contends that statements made by Respondents in explaining their dietary supplement beliefs are **commercial speech**, not political or religious speech. Complaint Counsel maintains that Respondents' commercial speech is not protected by the First Amendment because it contains statements about dietary supplements that fail the Supreme Court's threshold test that such statements "not be misleading."

In fact, Respondents' statements about dietary supplements, which are based on a religious view of life grounded in the Christian Bible and positioned as a political

argument against drugs and pharmaceutical companies, do qualify as religious and political speech.

Even if Respondents' statements about dietary supplements are found to be commercial speech and solely commercial speech, they are protected by the First Amendment. The FDA makes the point about dietary supplements and the claims made for them in its dietary supplement regulations. It says, "FDA does not believe that the rule violates the First Amendment. The rule does not prohibit any speech; rather, it clarifies the circumstances under which FDA will consider a certain type of speech -- labeling claims -- to be evidence of intended use as a drug, absent health claim authorization. Thus, the rule does not regulate speech as such, but rather as evidence of intended use." Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 4 (Jan. 6, 2000).

Complaint Counsel asserts that Respondents have failed to prove Respondents' statements concerning the Challenged Products are not misleading. Complaint Counsel offered no evidence that the Respondents intended for the Challenged Products to be seen to be, promoted as, or considered by consumers for use as drugs. On the contrary, the record establishes that Respondents' primary mission and intention was to present dietary supplements as the opposite of drugs. In fact, the mission of Daniel Chapter One, drawn from its Bible based views of the innate healing capacity of the body, rests on the assertion, belief and understanding by Respondents that the dietary supplements they discuss are not drugs.

Throughout this proceeding, Complaint Counsel has assumed that Respondents intended their products to be used as drugs and that therefore it is Respondents' burden to show that their commercial speech—to the extent that their speech is commercial speech--was scientifically supported. Consistent with that theory, Complaint Counsel has made no effort to show that Respondents' claims were, in fact, false or deceptive. In contrast, Respondents have presented evidence, including testimony of expert witnesses, that the statements they made about the supplements at issue were in fact supported by the scientific literature that address the herbs and natural substances that make up their products.

Complaint Counsel has chosen to argue not that expert information relied upon by Respondents was invalid or unreliable but rather that most of it was not supported by double blind, placebo controlled clinical studies. Based on this argument, Complaint Counsel has concluded that, since Respondents' statements concerning the Challenged Products have not met the requirements for approval of a drug by the FDA, those statements are not protected by the First Amendment. In short, Complaint Counsel has not established that Respondents intended for the Challenged Products to be used or treated as drugs but instead has assumed that the Challenged Products are drugs and further assumed that exceptions to First Amendment protection of speech require Respondents to prove that the Challenged Products meet the FDA standard for approval of a new drug. FTC Opp. Dismiss, p. 13; FTC Pre-Trial Br., p. 31.

Complaint Counsel's theory is based on false constitutional assumptions and is contrary to controlling Supreme Court precedent. In support of its argument that Respondents have failed to meet the non-misleading threshold test requiring an

A. The FTC Has the Burden to Prove Respondents' Statements Concerning the Challenged Products Are Misleading and to Prove That Its Suppression of Such Claims is a Direct and Necessary Means to Achieve a Substantial Government Interest.

According to Complaint Counsel, the U.S. Supreme Court established in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980) that commercial speech did not deserve First Amendment protection unless it is "not ... misleading." FTC Opp. Dismiss, p. 13. By stating the *Central Hudson* rule in the negative, Complaint Counsel has assumed that Respondents have the burden of showing that their statements relating to the Challenged Products have a "reasonable basis," which Complaint Counsel takes to mean contemporaneously supported by "competent and reliable scientific evidence" (defined as double-blind placebo controlled clinical studies). FTC Pre-Trial Br., p. 22. Complaint Counsel believes that unless Respondents meet this burden, Respondents have not shown that their statements are "not misleading." FTC Pre-Trial Br., p. 31. Complaint Counsel misreads and misapplies applicable law.

In 1995, the Supreme Court restated its *Central Hudson* formula in the affirmative, asserting that "the government may freely regulate commercial speech that ... is misleading." *Florida Bar v. Went For It, Inc.,* 515 U.S. 618, 623-24 (1995). By changing the threshold question from a requirement that the commercial statement be non-misleading, to a requirement that such statement be misleading, the Court conformed its statement of the *Central Hudson* rule to the several court decisions handed down in the 15 years after *Central Hudson* had been decided.

In 1982, the Supreme Court, applying *Central Hudson*, ruled that a particular attorney advertisement could not be "prohibited entirely," there being nothing in the

> It has **not demonstrated** with sufficient specificity that any member of the public could have been misled by Ibanez' constitutionally protected speech or that any harm could have resulted from allowing that speech to reach the public's eyes. [*Ibanez*, 512 U.S. at 138-39 (emphasis added).]

Not only must the government agency that seeks to suppress commercial speech meet its burden to prove the commercial speech at issue to be false, misleading or deceptive, as a matter of fact, it must also "show[] that the restriction directly and materially advances a substantial state interest in a manner no more extensive than necessary to serve that interest." *Ibanez*, 512 U.S. at 142. Again, as the *Ibanez* Court emphasized, "[t]he State's burden is not slight; the free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful." *Ibanez.*, 512 U.S. at 143. Complaint Counsel in this case made no effort to meet this constitutionally mandated standard.

In *Edenfield v. Fane*, 507 U.S. 761 (1995), the Court explained that the government's "burden is not satisfied by mere speculation or conjecture," but only by "demonstrat[ing] that the harms [the government] recites are real and that restriction will in fact alleviate them to a material degree." *Edenfield*, 507 U.S. at 770-71. And later that same year, in *Rubin v. Coors Brewery Co.*, 514 U.S. 476, 487 (1995), the Court further stressed that unless this "critical" requirement is met, "a State could with ease restrict commercial speech in the service of ... objectives that could not themselves justify a burden on commercial speech." *Edenfield*, 507 U.S. at 771.

In sum, under the commercial speech doctrine invoked by Complaint Counsel, a long line of Supreme Court cases has demonstrated the requirement that "the Government bears the burden of **identifying** a substantial interest and **justifying** the challenged

restriction." *Greater New Orleans Broadcasting Ass'n, Inc. v. United States*, 527 U.S. 173, 183 (1999) (emphasis added). *Thompson v. Western States Medical Center*, 535 U.S. 357, 367-377 (2002). Complaint Counsel has failed to meet this burden.

B. The FTC Has Not Shouldered Its Burden to Prove that Respondents' Statements Concerning the Challenged Products Are Misleading.

As noted above, Complaint Counsel has produced absolutely no evidence that any person has, in fact, been misled by Respondents' statements concerning the Challenged Products. Rather, Complaint Counsel has maintained that Respondents' statements are "deceptive under the FTC Act if [they] are **likely to mislead** consumers, acting reasonably under the circumstances." FTC Pre-Trial Br., p. 10 [emphasis added]. Furthermore, in implementing the "'likely to mislead' standard," the "FTC examines the overall net impression" of ads, coupled with "its own reasoned analysis to determine what claims an advertisement conveys." FTC Pre-Trial Br., pp. 10-11. Thus, it dispenses with any burden of having to produce any actual consumer "to determine how 'reasonable consumers' interpret a claim." Indeed efforts by Respondents to introduce consumer testimony were opposed by Complaint Counsel and the opposition was upheld. FTC Pre-Trial Br., p. 11. Indeed, Complaint Counsel places the FTC, itself, into the shoes of "'desperate consumers with terminal illnesses'" to examine whether Respondents' statements concerning the Challenged Products are "likely to mislead."

In one of its earliest opinions applying its First Amendment commercial speech doctrine, the Supreme Court warned against this kind of "paternalistic approach" to protect "unwitting customers." *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 769-770 (1976). In that case, the Court stated:

> There is ... an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, that the best means to that end is to open the channels of communication rather than to close them... It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us. *Virginia State Board of Pharmacy,* 425 U.S. at 770.

This First Amendment principle is especially applicable to efforts by government agencies to suppress commercial speech by labeling it to be misleading on "the paternalistic assumption that the recipients of [an advertisement] are no more discriminating than the audience for children's television." *Peel*, 496 U.S. at 105.

In short, there is no First Amendment short-cut for the FTC to by-pass the consumers, actual or potential, of the Challenged Products, substituting its views of the allegedly "misleading impression" that Respondents' statements make on those consumers in place of either actual testimony from people to whom the information is directed or valid studies of such persons' responses to the statements. *Ibanez*, 512 U.S. at 148. *Edenfield v. Fane*, 507 U.S. 761, 771 (1993) (striking down Florida ban on CPA solicitation where Board "presents no studies that suggest personal solicitation ... creates the dangers ... the Board claims to fear," nor even "anecdotal evidence ... that validates the Board's suppositions."). Nor can the FTC justify its failure to produce such testimony or such studies on the ground that, because of its expertise, it "is in a far better position that is [a court] to determine which statements are misleading or likely to mislead." *Peel*, 496 U.S. at 108.

It appears, however, that Complaint Counsel seeks to avoid its First Amendment burden of proving that people are actually misled by Respondents' statements, because Respondents' statements are not supported by "competent and reliable scientific"

evidence defined as double-blind, placebo-controlled studies . FTC Pre-Trial Br., p. 21 ("Unsubstantiated Claims Are Misleading"). But Respondents have not made statements claiming to be based on evidence of that type; nor could anyone reasonably infer from Respondents' statements that their claims were based on double-blind, placebo-controlled studies. Consistent with its nature as a religious ministry, Respondents did present first-person testimonies from people actually using its products, but Complaint Counsel argues that whether Respondents products actually helped individuals improve their health is irrelevant, since it does not fall within the confines of their narrow view of "scientific evidence." FTC Pre-Trial Br., pp. 32-24. In any event, it is not Respondents' burden to furnish such studies. To the contrary, it is incumbent upon the FTC to produce evidence of the falsity of Respondents' claims.

Although Complaint Counsel has not expressly argued the point, it appears that it assumes that Respondents' statements concerning the Challenged Products are "inherently misleading" without reasonable basis, there being little or no double-blind, placebo controlled, clinical studies in evidence to support them. FTC Pre-Trial Br., pp. 25-27. To be sure, commercial speech that is "inherently misleading" does lose First Amendment protection,[12] but in the absence of proof establishing that claim the FTC has not, and cannot, satisfy its burden by asserting that it knows that Respondents' statements are "inherently misleading."

Indeed, the United States Court of Appeals for the District Columbia rejected a remarkably similar claim by the federal Food and Drug Administration ("FDA"). In *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), the FDA asserted "that health claims

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12 *In the Matter of R.M.J.*, 455 U.S. at 203.

lacking 'significant scientific agreement' are *inherently* misleading and thus entirely outside the protection of the First Amendment." *Pearson*, 164 F.3d at 655 (italics original). The court of appeals dismissed the government's claim as "almost frivolous," having no basis other than in an impermissible "paternalistic assumption" that any such health claim would have such an "awesome impact on consumers as to make it virtually impossible for them to exercise any judgment *at the point of the sale." Pearson.*, 164 F.3d at 655 (italics original). Complaint Counsel disregards this court finding.

C. The FTC Has Not Carried Its Burden to Show That Censoring Respondents' Statements Concerning the Challenged Products Meets the Three-Part Test of *Central Hudson*.

As pointed out above, the FTC bases its argument on asserting that Respondents' statements concerning the Challenged Products constitute "commercial speech." In its first case "in which [it] explicitly held that commercial speech receives First Amendment protection," the Supreme Court "explained the reasons for this protection"[13]:

> It is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed. To this end the free flow of commercial information is indispensable."... Indeed, we recognized that a particular consumer's interest in the free flow of commercial information ... may be as keen, if not keener, by far, than his interest in the day's most urgent political debate. *Thompson*, 535 U.S. at 366-67.

Additionally, the Court has "emphasized":

> The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented. Thus, even a communication that does no more than propose a commercial transaction is entitled to coverage of the First Amendment. *Thompson*, 535 U.S. at p. 367.

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13 *Thompson v. Western States Medical Center*, 535 U.S. at 366.

Certainly, the record shows that Respondents' statements concerning the Challenged Products fall squarely within the Supreme Court's First Amendment umbrella. The people seeking out Respondents' information are looking for natural and faith-based approaches to address their life situations.

In recognition of the First Amendment commitment to keep the channels of communication open, the Supreme Court has imposed strict rules designed to limit government efforts to close the door, insisting that any such regulation must "directly advance" a "substantial government interest" by a regulation that is "not more extensive than is necessary to serve that interest." *Thompson*, 535 U.S. at 367. Because Complaint Counsel has mistakenly assumed that Respondents' commercial speech is not protected by the First Amendment, it has also mistakenly assumed that it need not comply with this First Amendment rule.

As a result of this approach, Complaint Counsel has introduced no evidence that its suppression of Respondents' statements concerning the Challenged Products would directly advance a substantial government interest and that such suppression is not more extensive than is necessary to serve that interest. Indeed, Complaint Counsel has not even asserted that its effort to suppress Respondents' statements concerning the Challenged Products is pursuant to an effort to directly advance a substantial government interest by a means not more extensive than necessary. Instead, all that Complaint Counsel has attempted to show is that Respondents' statements concerning the Challenged Products are "unsubstantiated" by any "competent and reliable scientific evidence" as defined solely as double-blind, placebo-controlled studies. FTC Pre-Trial Br., pp. 21-29.

As pointed out above, it is the FTC's, not Respondents', burden to meet that First Amendment test. Having utterly failed even to attempt to carry its burden to meet that test, the FTC has no authority to pursue a remedy in this proceeding. Consequently, the Complaint should be dismissed.

CONCLUSION

Complaint Counsel has failed to establish a constitutionally-valid predicate for action against Respondents, and has failed to prove a violation of the FTC Act. Consequently, this action should be dismissed with prejudice.

Dated: May 28, 2009

Respectfully Submitted,

Michael McCormack
26828 Maple Valley Hwy, Suite 242
Maple Valley, WA 98038
Phone: 425-785-9446

James S. Turner
Betsy E. Lehrfeld
Christopher B. Turner
Swankin & Turner
1400 16th Street NW, Suite 101
Washington, DC 20036
Phone: 202-462-8800
Fax: 202-265-6564

Of Counsel:

Herbert W. Titus
William J. Olson
John S. Miles
Jeremiah L. Morgan
William J. Olson, P.C.
8180 Greensboro Drive, Suite 1070
McLean, VA 22102-3860
Phone: 703-356-5070
Fax: 703-356-5085
Email: wjo@mindspring.com

IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF THE ADMINISTRATIVE LAW JUDGES

In the Matter of	)	
DANIEL CHAPTER ONE,	)	**DOCKET NO. 9329**
a corporation, and	)	
	)	
	)	**PUBLIC DOCUMENT**
JAMES FEIJO,	)	
Individually, and as an officer of	)	
Daniel Chapter One.	)	
	)	

RESPONDENTS' PROPOSED FINDINGS OF FACT

Respondents' Proposed Findings of Fact

1. Respondent Daniel Chapter One (hereinafter "DCO") is a non-profit corporation sole organized under Washington State law. (CX 31; CX 35; R 1; R 2).

2. Respondent DCO is a religious ministry. (HOJ*, ALJ, Tr. 7; R 1; Harrison, Tr. 280, 290-299; Feijo, P., Tr. 344-345, 382-384; Feijo, J., Tr. 416-417, 464).

3. Corporate Respondent DCO has no for-profit members. (R 1; R 15 (Feijo, J., Dep. at 181-189)).

4. Respondent James Feijo is the overseer of DCO, and as such he holds all DCO property in trust for the ministry. (Feijo, J., Tr. 416).

5. Respondent James Feijo has taken a vow of poverty as overseer of DCO's ministry. (R 15 (Feijo, J., Dep. at 151)).

6. Respondent DCO's name "Daniel Chapter One" refers to the chapter and verse of the Bible dealing with nutrition and natural healing. (Feijo, P., Tr. 327-328).

7. Respondents' speech is intended to educate and inform recipients about health and healing practices that are consistent with the Book of Daniel, Chapter One, and other parts of the Bible.

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* Hearing on Jurisdiction

(Harrison, Tr. 279-284, 286-291, 298-299, 312; Feijo, P., Tr. 327-328, 337-339, 343-345, 357-358, 368-372, 382-383; Feijo, J., Tr. 416-417, 422-431, 433-436, 456-457).

8. Respondents' speech is intended to reach those who are devoted to or interested in nutrition and natural healing as expressed by the DCO ministry and the Book of Daniel, Chapter One, and other parts of the Bible. (Harrison, Tr. 279-284, 286-291, 298-299, 312; Feijo, P., Tr. 327-328, 337-339, 343-345, 357-358, 368-372, 382-383; Feijo, J., Tr. 416-417, 422-431, 433-436, 456-457).

9. Respondents communicate the message of their ministry by traveling the world for community meetings and prayer groups, and by using the internet, live radio broadcasts and written publications, and by including a Bible verse on labels of each of the Challenged Products. (CX 18 at FTC-DCO 0122, 0124, 0125, 0127; Harrison, Tr. 279-284, 286-291, 298-299, 312; Feijo, P., Tr. 327-328, 337-339, 343-345, 357-358, 368-372, 382-383; Feijo, J., Tr. 416-417, 422-431, 433-436, 456-457).

10. As part of their ministry, Respondents express opinions via their radio broadcasts and their written publications about nutrition and natural healing. (Harrison, Tr. 279-284, 286-291, 298-299, 312; Feijo, P., Tr. 327-328, 337-339, 343-345, 357-358, 368-372, 382-383; Feijo, J., Tr. 416-417, 422-431, 433-436, 456-457).

11. Respondents offer dietary supplement products (DCO products), including the Challenged Products, as part of their overall ministry. (Feijo, P., Tr. 337-338; 342-343).

12. The Challenged Products are four of close to 200 products offered by Respondents. (Feijo, P., Tr. 392).

13. Respondents use radio broadcasting and personal appearances as the primary means of informing interested persons about DCO products. (Feijo, J., Tr. 279-280; 282-284).

14. Interested persons who wish to obtain DCO products do so through the website. (Feijo, J., Tr. 459-450, 464).

15. Where the Challenged Products appear and are ordered on Respondents' website(s), the following language appears:

> "The information on this website is intended to provide information, record, and testimony about God and His Creation. It is not intended to diagnose a disease. The information provided on this site is designed to support, not replace, the relationship that exists between a patient/site visitor and his/her health care provider. Caution: some herbs or [nutritional] supplements should not be mixed with certain medications." (CX 11; CX 17 at FTC-DCT 0071, 0074, 0077, 0081, 0085-0086, 0090, 0093, 0096, 0099).

16. With respect to the Challenged Products, Respondents' website(s) contain the following disclaimer:

"These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent disease." (CX 17 at FTC-DCO 0073, 0076, 0080, 0084, 0089, 0095, 0098; Feijo, P., Tr. 382).

17. The Challenged Products are intended to supplement the diet, through the use of a vitamin, mineral, herb, or other botanical, for use by man to increase the total daily intake of such ingredients. (Feijo, P., Tr. 394; Feijo, J., Tr. 442-444, 457, 459).

18. Respondents do not claim that the Challenged Products treat disease. (Feijo, P., Tr. 442-444).

19. The Challenged Products are intended for ingestion in capsule, powder, or liquid form. (Feijo, J., Tr. 446).

20. The Challenged Products are not represented for use as a conventional food or as the sole item of a meal or diet. (Feijo, J., Tr. 446).

21. The Challenged Products are labeled as dietary supplements. (CX 12; CX 13; CX 14; CX 15; CX 16; CX 18 at FTC-DCO 0122, 0124, 0125, 0127).

22. On their website, Respondents make the following claim about the Challenged Product Bioshark:

"Pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis -- the formation of new blood vessels. This can stop tumor growth and halt the progression of eye diseases . . ." (CX 12; Feijo, P., Tr. 341-342).

23. On their website, Respondents make the following claim about the Challenged Product 7 Herb Formula:

"purifies the blood, promotes cell repair, fights tumor formation, and fights pathogenic bacteria" (CX 13; Feijo, P., Tr. 345-346).

24. On their website, Respondents make the following claim about the Challenged Product GDU:

"contains natural proteolytic enzymes (from pineapple source bromelain to help digest protein --even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. . .GDU is also used for. . .and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. . ." (CX 14; Feijo, P., Tr. 351-352).

25. On their website, Respondents make the following claim about the Challenged Product BioMixx:

"boosts the immune system, cleanses the blood and feeds the endocrine system to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments." (CX 15; Feijo, P., Tr. 354-355).

26. Respondents do not use the words *diagnose*, *mitigate*, *cure* or *prevent* in any representation they make about the Challenged Products. (Feijo, P., Tr. 338-341; 345-346; 351-352; 354-355; 412-413).

27. The express statements made by DCO about the Challenged Products describe the supplement's effects on the "structure or function" of the body. (Feijo, P., Tr. 345-357; 379-392).

28. The literature relied on by Respondents for their claims about the Challenged Products constitutes competent and reliable scientific evidence. (LaMont, Tr. 596).

29. Respondents relied on literature consisting of articles, publications and expert analysis to substantiate their statements about the Challenged Products. (R 9; R 10; Feijo, P., Tr.. 401-402, 404-405, 605-610).

30. The substantiating literature used by Respondents for their claims about the Challenged Products is consistent with the general research available about the constituent ingredients of the Challenged Products. (R 9; R 10; LaMont, Tr. 587-588).

31. There is no evidence in the record that Respondents' statements about the Challenged Products caused harm or potential harm to consumers. (Entire record).

32. There is no evidence in the record that the Challenged Products have caused actual harm to consumers. (Entire record).

33. There is no evidence in the record that the FTC has received any complaints concerning the Challenged Products. (R 11 (Marino, Dep. at 49-51); entire record).

34. There is no evidence in the record of any investigation or analysis concerning consumer expectations or perceptions about the Challenged Products. (Entire record).

35. There is no evidence in the record concerning consumer expectations and perceptions about the Challenged Products. (Entire record).

36. The cost to substantiate the "structure and function" claims made by the Respondents about the Challenged Products is unproven by Complaint Counsel, but is likely to be in excess of $100 million per constituent ingredient. (R 14 (Miller, Dep. at 49); Miller, Tr. 149, 181).

37. The expert witness offered by Complaint Counsel did not address Respondents' express statements about the Challenged Products, but only addressed claims of cancer treatment allegedly implied by Respondents. (Miller, Tr. 150-152).

38. The expert witness offered by Complaint Counsel did not know the meaning or significance of a "structure/function" claim. (Miller, Tr. 173-174).

39. The expert witness offered by Complaint Counsel did not have knowledge of the type of statements for dietary supplements permitted by the FDA under DSHEA. (Miller, Tr. 150-152, 204).

40. The expert witnesses offered by Respondents did address Respondents' express statements about the Challenged Products, and concluded that those claims are accurate. (RX 3; RX 4; Duke, Tr. 519-520; LaMont, Tr. 572-574).

41. Respondent's expert witness analyzed the meaning and significance of "structure/function" claims. (R 4; LaMont, Tr. 550-551, 574-575).

42. The expert witnesses offered by Respondents testified competently that the cost of substantiating "structure/function" claims for dietary supplements in the same manner as drugs is prohibitive. (Duke, Tr. 536-538; LaMont, Tr. 595-597).

43. There are valid scientific, fiscal and competitive reasons for requiring lesser substantiation for dietary supplement claims as compared to pharmaceutical drug claims. (LaMont, Tr. 596-597).

44. The expert witnesses offered by Respondents testified competently that the amount of substantiation that exists to support Respondents' claims about the Challenged Products is reasonable. (LaMont, Tr. 595-599).

45. Competent and reliable scientific evidence exists for the claims made by Respondents about the Challenged Products. (LaMont, Tr. 599-600).

46. There is a reasonable basis for Respondent's claims about the biological mechanisms of the Challenged Products. (LaMont, Tr. 599).

IN THE UNITED STATES OF AMERICA
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OFFICE OF THE ADMINISTRATIVE LAW JUDGES

In the Matter of **DANIEL CHAPTER ONE,** **a corporation, and**	)	**DOCKET NO. 9329**
JAMES FEIJO, **Individually, and as an officer of** **Daniel Chapter One.**	)	**PUBLIC DOCUMENT**

RESPONDENTS' PROPOSED CONCLUSIONS OF LAW

Respondents' Proposed Conclusions of Law

1. Complaint Counsel has the burden of proving all elements of the charges against Respondents by clear, cogent and convincing evidence. *Addington v. Texas*, 441 U.S. 418 (1970).

2. Respondent DCO is a religious ministry. Revised Code of Washington § 24.12.

3. The opinions expressed by Respondents via their radio broadcasts and their written publications about nutrition and natural healing are religious opinions. *Trinidad v. Sagrada Orden de Predicadores*, 263 U.S. 578 (1924); *Saint Germain Foundation v. Commissioner*, 26 T.C. 648 (1956).

4. To prove the charge of unfair advertising under 15 U.S.C. § 45(n), Complaint Counsel must prove that Respondents' acts or practices caused or are likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. 15 U.S.C. § 45(n).

5. Complaint Counsel must prove that Respondents' acts or practices caused or are likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. 15 U.S.C. § 45(n).

6. The FTC employs a "reasonable basis" test for determining whether an advertisement is deceptive or misleading. *Pfizer*, 81 F.T.C. 23 (1972); *FTC v. Pharmatec*, 576 F. Supp. 294, 302 (D.D.C. 1983).

7. The "reasonable basis" test includes proof about the degree to which consumers will rely on the claim. *Pfizer*, at 64 and *Pharmatec*, at 302.

8. Complaint Counsel offered no evidence about the degree to which consumers rely on Respondents' claims. *Pfizer*, 81 F.T.C. 23 (1972); *FTC v. Pharmatec*, 576 F. Supp. 294, 302 (D.D.C. 1983).

9. Complaint Counsel's charges against Respondent are based on an "overall net impression" of false, deceptive and/or misleading advertisements. *Thompson Medical v. FTC,* 791 F.2d 189 (D.C. Cir. 1986).

10. To prove an "overall net impression" case, Complaint Counsel must prove with substantial evidence what the consumer expectations are regarding the Respondents' product claims. *Thompson Medical*, 104 F.T.C. 648 (1984), *aff'd* 791 F.2d 189 (D.C. Cir. 1986); *accord*, *Thompson* Policy Statement at p. 2.

11. Absent actual evidence of consumer expectations, the FTC's substantial evidence must address the following 6 factors:

- The type of claim;
- The Products;
- The consequences of a false claim;
- The benefits of a truthful claim;
- The cost of developing substantiation for the claim; and
- The amount of substantiation experts in the field believe is reasonable.

Thompson Policy Statement at p. 2.

12. Complaint Counsel must prove consumer expectations from the perspective of a reasonable member of Respondents' intended audience. *Cliffdale Associates*, 103 F.T.C. 110, and *Cliffdale Statement on Deception* at 174 (1984).

13. Complaint Counsel must prove the elements of its Overall Net Impression case with admissible extrinsic evidence. *Cliffdale Associates*, 103 F.T.C. 110 (1984); *see also Thompson*, 791 F.2d at 197.

14. Complaint Counsel may not prove the elements of its Overall Net Impression case by presumption. *Matthews v. Eldridge*, 424 U.S. 319, 332 (1976); *Stanley v. Illinois,* 405 U.S. 645, 656-657 (1972).

15. Complaint Counsel has not produced extrinsic evidence to support its "overall net impression" charges against Respondent. *Cliffdale Associates*, 103 F.T.C. 110 (1984); *see also Thompson*, 791 F.2d at 197.

16. The Challenged Products are dietary supplements. 21 U.S.C. § 321(ff).

17. Respondents' statements about the Challenged Products are structure/function claims allowed by DSHEA. 21 U.S.C. § 343(r)(6).

18. The literature relied on by Respondents to support the structure/function claims made about

the Challenged Products was reasonable. *FTC Guide: Dietary Supplements, An Advertising Guide for Industry*, p. 10.

19. Double blind placebo studies and clinical trials are not necessary to substantiate structure/function claims about dietary supplements. *FTC v. QT*, 512 F.3d 858, 861 (7th Cir. 2008).

20. Complaint Counsel's proffered expert, Dr. Miller, is qualified to testify on the subject of cancer treatment and cancer treatment claims, but not on the subjects of dietary supplements, dietary supplement structure/function claims, the substantiation for such claims or the amount of substantiation for such claims that qualifies as reasonable. *Dietary Supplements: An Advertising Guide for the Industry, and Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

21. The claims made by Respondents cannot be regulated under the Commercial Speech Doctrine. *Central Hudson Gas & Electric Corp. v. Pub. Service Comm'n*, 447 U.S. 557 (1980).

22. The claims made by Respondents cannot be regulated under the First Amendment to the U.S. Constitution. (U.S. Const. amend. I).

23. Dr. Miller's testimony on the subject of cancer treatment and cancer treatment claims was not relevant. *Dietary Supplements: An Advertising Guide for the Industry, and Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

24. Respondents' experts James Duke and Dr. Sally LaMont are qualified to testify on the subjects of dietary supplements, dietary supplement structure/function claims, the substantiation for such claims or the amount of substantiation for such claims that qualifies as reasonable. *Dietary Supplements: An Advertising Guide for the Industry, and Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

25. James Duke's testimony on the subjects related to dietary supplements was relevant. *Dietary Supplements: An Advertising Guide for the Industry, and Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

26. Dr. LaMont's testimony on the subjects related to dietary supplements was relevant. *Dietary Supplements: An Advertising Guide for the Industry, and Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

27. The testimony of Respondents' qualified and relevant experts that Respondents' claims are supported by competent and reliable scientific evidence, meets the FTC standard for substantiation. *Dietary Supplements: An Advertising Guide for the Industry.*

28. Respondents' claims concerning the biological mechanisms underlying the Challenged Products are substantiated and have a reasonable basis. 21 U.S.C. § 343(r)(6).

IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
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In the Matter of	)	**Docket No.: 9329**
DANIEL CHAPTER ONE,	)	
a corporation, and	)	
JAMES FEIJO,	)	**PUBLIC DOCUMENT**
individually, and as an officer of	)	
Daniel Chapter One	)	
	)	
	)	
	)	
	)	

[PROPOSED] ORDER DISMISSING COMPLAINT

The hearing in the administrative action *In the Matter of Daniel Chapter One*, Docket No. 9329 having concluded, the record being closed, counsel for both parties having briefed the relevant issues, and the Court being fully advised,

THE COURT FINDS:

1. Respondents Daniel Chapter One and James Feijo have not violated Sections 5 and 12 of the FTC Act;
2. Respondents' statements concerning the Challenged Products are not untruthful or misleading and are substantiated by competent and reliable scientific evidence; and
3. Respondents' statements concerning the Challenged Products are protected speech under the First Amendment to the United States Constitution.

THEREFORE, IT IS ORDERED that the administrative action *In the Matter of Daniel Chapter One*, Docket No. 9329, be, and is hereby DISMISSED WITH PREJUDICE against all Respondents.

Dated this___ day of _____, 2009.

_____
D. Michael Chappell
Administrative Law Judge

IN THE UNITED STATES OF AMERICA
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DANIEL CHAPTER ONE,	)	**DOCKET NO. 9329**
a corporation, and	)	
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JAMES FEIJO,	)	
Individually, and as an officer of	)	
Daniel Chapter One.	)	
	)	

RESPONDENTS' INDEX OF EXHIBITS

EXHIBIT NUMBER	EXHIBIT TITLE	RELEVANT TRANSCRIPT PAGES
R1	Certificate of Existence/ Authorization and Articles of Incorporation of Daniel Chapter One	5; 230 HOJ* 19-20; 87-100;
R2	Revised Code of Washington, §§ 24.12.010 *et seq.*	5; 230
R3	Expert Witness Report of James Duke	5; 23; 93-94; 230; 472-505; 508-538; 590
R4	Expert Witness Report of Sally LaMont	5; 93-94; 230; 275; 539-563; 565-587; 590; 595-600
R5	Expert Witness Report of Rustum Roy	5; 93-94; 230; 251-253; 590
R6	Expert Witness Report of James Dews	5; 93-94; 230; 251-252; 590
R7	Expert Witness Report of Jay Lehr	5; 93-94; 230; 590
R8	Testimonials from Constituents of Respondents' Ministry and Users of DCO Products	230; 578; 585-586; 588-595
R9	References Relied on by Respondents to Substantiate their Statements	588-595; 601-610
R10	List of Documents Substantiating Challenged Claims	5; 230; 274-277; 587-595; 599-610
R11	Deposition Transcript – Michael Marino	5; 230; 252; 265-266; 305; 313; 316; 358-359; HOJ* 321

* HOJ – Hearing on Jurisdiction held on April 21, 2009.

R12	*Not admitted*	
R13	*Not admitted*	
R14	Deposition Transcript – Denis R. Miller	5; 149; 158; 218-219; 230; 252; 330; 370; 406-408
R15	Deposition Transcript – James D. Feijo	5; 85; 229-230; 252; 330; 420 HOJ* 321
R16	Deposition Transcript – Patricia A. Feijo	5; 85; 229-230; 252; 330 HOJ* 321
R17	Deposition Transcript – Claudia Bauhoffer-Kinney	5; 229-230; 252; 330 HOJ* 239; 109;
R18	Deposition Transcript (with exhibits) – James A. Duke	5; 230; 252; 330
R19	Deposition Transcript (with exhibits) – James Dews	5; 25-26; 230; 252; 330
R20	Deposition Transcript (with exhibits) – Rustum Roy	5; 23-24; 230; 252; 330
R21	Deposition Transcript (with exhibits) – Jim Lehr	5; 24-25; 230; 252; 330
R22	Deposition Transcript (with exhibits) – Sally LaMont	5; 25; 230; 252; 275; 330

NOTES:

1. No exhibits have been accorded *in camera* treatment.
2. On page 5 of the transcript, the ALJ ruled that R1, R2, R3, R4, R5, R6, R7, R10, R11, R14, R15, R16, R17, R18, R19, R20, R21, and R22 are admissible via Joint Exhibit 1.
3. On page 230 of the transcript, the ALJ ruled that R8 and R9 are admissible via Joint Exhibit 2.
4. On page 586 of the transcript, the ALJ ruled that R8 is admissible as evidence of the nature of DCO's audience, and not for the truth of the testimonials.
5. On page 610 of the transcript, the ALJ ruled that R9 is admissible as evidence that Respondents relied on materials to substantiate their claims, and not for the truth of the materials.
6. There are no exhibits which summarize the contents of any listed exhibit, or of any other exhibit of which the listed exhibit is a summary.
7. There are no exhibits that cross-reference, by exhibit number, to any other portions of that document admitted as a separate exhibit on motion by any other party.

IN THE UNITED STATES OF AMERICA
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In the Matter of **DANIEL CHAPTER ONE,** **a corporation, and** **JAMES FEIJO,** **Individually, and as an officer of** **Daniel Chapter One.**	)	**DOCKET NO. 9329** **PUBLIC DOCUMENT**

RESPONDENTS' INDEX OF WITNESSES

Witness Name	Witness Description	Relevant Transcript Pages
Jedediah Harrison	Mr. Harrison is self-employed in the field of radio production and has worked extensively with the Feijos on the technical aspects of DCO's radio program. Mr. Harrison also does work related to DCO's Accent Radio Network website.	278-313
Patricia Feijo	Mrs. Feijo is the wife of James Feijo and is the co-founder and secretary of DCO. Mrs. Feijo's other responsibilities at DCO include: practicing homeopathy, writing, and conducting the radio program with Mr. Feijo.	324-413; 605-609
James Feijo	Mr. Feijo is the co-founder and overseer of DCO. He is actively involved in the Christian ministry and seeks to spread the word of spiritual healing through DCO.	415-464
Dr. James Duke	Dr. Duke is a retired economic botanist from the U.S. Department of Agriculture. He is an expert on herbal medicine.	472-538
Dr. Sally LaMont	Dr. LaMont is a naturopathic practitioner. She is an expert on herbal remedies.	539-600

NOTES:

No witnesses have been accorded *in camera* treatment.

CERTIFICATE OF SERVICE

I certify that on May 28, 2009, I filed, served or caused to be served or filed, the following documents on the individuals listed below as noted:

Respondents' Post Hearing Brief and Related Documents

The original and one paper copy via hand delivery and one electronic copy via email to:

Donald S. Clark
Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW, Room H-135
Washington, DC 20580
Email: secretary@ftc.gov

One paper copy via Federal Express (for delivery on May 29, 2009) and one electronic copy to each to:

Leonard L. Gordon, Esq. (lgordon@ftc.gov)
Theodore Zang, Jr., Esq. (tzang@ftc.gov)
Carole A. Paynter, Esq. (cpaynter@ftc.gov)
David W. Dulabon, Esq. (ddulabon@ftc.gov)
William H. Efron, Esq. (wefron@ftc.gov)
Federal Trade Commission – Northeast Region
One Bowling Green, Suite 318
New York, NY 10004

One electronic copy to:

Elizabeth Nach, Esq. (enach@ftc.gov)

Two paper copies via hand delivery and one electronic copy to:

Hon. D. Michael Chappell
Administrative Law Judge
600 Pennsylvania Avenue, NW, Room H-106
Washington, DC 20580
Email: oalj@ftc.gov

Martin R. Yerick
Swankin & Turner
1400 16th Street, NW, Suite 101
Washington, DC 20036